Primary Percutaneous Coronary Intervention (PPCI) Project Guidelines

As revised and approved on 9/4/14 by the Invasive Cardiac Services Advisory Committee (ICSAC)

These Guidelines apply to hospitals without cardiac surgery on site that applied to perform PPCI prior to April 17, 2014.

Massachusetts Department of Public Health

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[1] The monthly report is currently an excel spreadsheet sent to the DPH Bureau of Health Care Safety and Quality Complaint Unit. This information will eventually be reported through the Bureau's electronic reporting system.

PPCI Guidelines for Hospitals without Cardiac Surgery On Site

I. Objectives of the PPCI Project

A. to provide a mechanism for hospitals that do not have on-site open heart surgery the capacity to perform PPCI.

B. to provide the Department of Public Health (Department) with relevant information to assist in its assessment of the safety and efficacy of the performance of PPCI in hospitals without on-site cardiac surgery.

II. Description of the PPCI Project

These Guidelines apply to hospitals without cardiac surgery on site that applied to perform PPCI prior to April 17, 2014.

A. Hospitals must:

1. have submitted an application prior to April 17, 2014 to perform this service.
2. completed prescribed training and provide ongoing education programs.
3. established a collaborative relationship with a tertiary hospital that has on site open-heart surgery (SOS hospital).
4. established a Joint Quality Assurance Committee with the relevant collaborating tertiary hospital.
5. adhere to the PPCI protocol including the selection of patients, data collection, in-service education and reporting to the Department of any serious events involving a patient.
6. collect and submit all data required by the Department and ensure all relevant medical record data, at the discretion of the Department, is available to the Department.
7. provide PPCI availability at the project hospital 24 hours a day, seven days a week, 365 days per year.
8. perform a <u>minimum</u> of 36 PPCI procedures/year.

III. Minimum Criteria for Ongoing Participation in the Project

A. The hospital has a designated "Physician Director", "Nurse Coordinator" and "Data Coordinator" for the project at that hospital. The Physician Director is responsible for overseeing the development and implementation of the project at that hospital. The Physician Director is also responsible for assuring that the project hospital's program is in full compliance with all requirements of the project at that hospital. The Physician Director and the Nurse Coordinator will serve as the staff contacts for all parties. The Data Coordinator assures that all required data is collected and archived in patient charts.

B. The hospital must maintain a current, signed collaboration agreement (See IV and Attachment A) with a tertiary hospital that has on site open-heart cardiac surgery services. Among the issues to be addressed in the collaboration agreement is the transfer of patients in whom a procedural complication warrants surgical intervention. Transport to a hospital providing cardiac surgical support requires rapid and efficient transfer, specifically: ambulance transport must be on site or arrive on-site at the non-SOS hospital within 30 minutes of request by catheterization staff due to procedural

complication. Every effort must be made to ensure arrival of the patient at the SOS hospital within 60 minutes of decision to transport the patient.

C. Each hospital must:
    1. perform ***at least*** 300 diagnostic catheterizations annually.
    2. perform a ***minimum*** of **36** PPCI procedures/year.
    3. provide PPCI 24 hours per day, 7 days per week, 365 days per year.
    4. have ***at least*** 2 physicians on the staff who are board certified in Interventional Cardiology, have active ACLS certification, and actively participate in the performance of PPCI procedures at the Project hospital.
        a. these physicians shall perform no fewer than 50 PCIs per year (averaged over two years); and
        b. each of the physicians participating in the Project will maintain credentials at a hospital at which that operator performs elective PCI procedures.
    5. have staff and services consistent with the following:
        a. the Emergency Department is continuously staffed by personnel competent in performing an ECG, initial evaluation and treatment of patients with acute ischemic syndromes including myocardial infarction and unstable angina. Appropriate monitoring equipment is be available, staff are trained in cardiac monitoring and advanced cardiac life support (ACLS), and staff maintain current ACLS certification.
        b. ability to provide routine lab testing and radiographic studies.
        c. intensive care unit usually has cardiac monitoring, immediate access to persons trained in ACLS; and capabilities for arterial line and pulmonary artery catheter placement, temporary pacemaker placement and mechanical ventilation. ICU staff are competent in the administration of all forms of vasoactive continuous IV infusions. Nursing staff are competent in the recognition and treatment of arrhythmias and evaluation of ischemic symptoms.
        d. intra-aortic balloon equipment and staff trained in the use of this equipment are immediately available.
        e. intermediate care unit can provide continuous ECG monitoring and prompt access to personnel trained in ACLS, with current ACLS certification. Personnel are competent in recognition of arrhythmias and evaluation of ischemic symptoms; in the administration of some forms of vasoactive drips [e.g., low-dose dopamine, dobutamine, or nitroglycerine (NTG) infusion]; and in the care of patients with a temporary pacemaker already in place.
        f. All "second operators" for PCI procedures must either be a physician or a technician, RN, NP or PA who is trained in the performance of PCI procedures through direct observation of at least 25 PCI procedures within the past two years. If the second operator is also to assist at driving/moving the cath table and thus the performance of the fluoroscopy, that individual must satisfy DPH regulations pertinent to the operation of fluoroscopy.

IV. Collaborative Association with Tertiary Hospital

A. All hospitals participating in the Project must:

1. establish a collaborative association with a tertiary hospital to specifically meet the requirements of the Project.
   a. the purpose of this association is to provide the Project hospital's staff ongoing support and expertise in the care of patients undergoing a PPCI procedure.
2. maintain a signed, current collaboration agreement with a tertiary hospital.

B. Responsibilities of the tertiary hospital shall, at a minimum, include:

1. provision of ongoing, 24-hour availability of consultation to the physicians and nursing staff in the care of patients that are candidates for and/or have PPCI performed.
2. development with and participation in a ***joint*** quality assurance program, with the participant hospital, which includes all disciplines (i.e., physicians, nurses and technicians from the staffs of both the participating Project hospital and the collaborating tertiary hospital) providing patient care and focuses on patient outcomes.
3. provision for occasions of clinical training, at the tertiary hospital, of the staff of the Project hospital in preparation for performing PPCI at the Project hospital.
4. development with the participant hospital of a training program for all new staff (including, at a minimum, all interventional cardiologists, nurses and technicians).
5. development of and participation in ***joint*** in-service education programs for *all staff* (including physicians, nurses and technicians) at the Project hospital. The in-service education programs will be based upon needs identified in the processes of staff evaluation and the QA program.

C. The Collaboration Agreement will:

1. be specific to the requirements of the Project and be developed through the participation of all appropriate disciplines. At a minimum, this includes physicians, nurses and hospital administrators from the staffs of both the participating Project hospital and the collaborating tertiary hospital. See Attachment A for Guidelines to be used in the development of the Collaboration Agreement.
2. delineate the development of a ***joint*** quality assurance review program which includes physicians and nurses from the staffs of both the participating Project hospital and the collaborating tertiary hospital and focuses on patient outcomes (See V, G).
3. delineate the development of **joint** educational programs to include all groups of staff (physicians, nurses and technicians) at the Project hospital
4. include specific provisions for the emergency and routine transfer of patients. For patients in whom a procedural complication warrants surgical intervention, transport to a hospital providing cardiac surgical support requires rapid and efficient transfer, specifically: ambulance transport must be on site or arrive on-site at the non-SOS hospital within 30 minutes of request by

catheterization staff due to procedural complication. Every effort must be made to ensure arrival of the patient at the SOS hospital within 60 minutes of decision to transport the patient.

V. Protocol

A. Clinical Protocol

1. Clinical selection criteria

The following criteria must be met for the selection of patients for the performance of PPCI:

a. The patient is 18 or more years of age

b. The patient presents with:

1. ongoing ischemic cardiac pain

and

2. ≥ 0.1 mv ST-segment elevation in 2 or more contiguous ECG leads
or
new or suspected new LBBB
or
≥0.1 mv ST-segment depression in V1 and V2 consistent with true posterior infarction

and

3. can have a PPCI procedure performed ("balloon inflation") within 90 minutes of ED arrival ("D2B").

For any case in which a PCI is performed on a patient who does not strictly meet these inclusion criteria, the hospital shall inform DPH in writing within 24 hours that the procedure was performed and the clinical reasons for proceeding with the case. This report must include any complications that occurred during and after the procedure, as well as whether the patient remains at the treating hospital or was transferred to a tertiary facility. If the patient was transferred, the reason for transfer must be stated.

2. Clinical exclusion criteria

Patients will be excluded from PPCI procedures at a Project hospital if any of the following conditions apply:

a. The patient has experienced > 12 hours of ongoing pain ("late presenter" or completed MI).

B. Informed consent

Consent for the performance of a cardiac catheterization procedure and possible PCI is to be obtained consistent with the policies and procedures of the hospital. The informed consent document must include language that states the hospital does not have cardiac surgery on site, explains the risks associated with not having cardiac surgery on site and the implications if there is a complication requiring cardiac surgery. The signed "Informed Consent" form is to be archived in the patient's hospital chart.

C. Ambulance service availability
Ambulance transport must be on site or arrive on-site at the non-SOS hospital within 30 minutes of request by catheterization staff due to procedural complication. Every effort must be made to ensure arrival of the patient at the SOS hospital within 60 minutes of decision to transport the patient.

D. Anesthesia services
Physician anesthesia services shall be immediately available on site when PPCI procedures are performed.

E. Notification of Department
1. Hospitals participating in the PPCI Project must report the following events to the Department within 30 days:
   a. death during hospitalization or within 24 hours of hospital discharge.
   b. emergency CABG within 24 hours of procedure.
   "Emergency" is defined as a sudden and often life-threatening mishap that arises in the course of and ***as a result of*** the performance of a cardiac catheterization and/or PCI procedure. This does not include patients either transferred directly from the cardiac catheterization procedure room or taken within 24 hours to the operating room for surgical correction of emergent/life threatening cardiac disease.

F. Data Collection
1. Consistent with the DPH hospital licensure regulations at 105 CMR 130.1303, each hospital that provides angioplasty[2] services shall submit patient-specific data to the NCDR National Database and to Mass-DAC for all of its patients who have angioplasty procedures. The hospital shall submit these data to the NCDR National Database in full compliance with the NCDR National Database's requirements. The hospital shall submit these data to Mass-DAC in a manner defined by the Department using NCDR National Database Standards and in accordance with requirements set forth by the Department.
2. All hospitals participating in the Project will provide monthly reports (See Attachment B) to the Department's Bureau of Health Care Safety and Quality's Complaint Unit through its electronic reporting system.

G. Quality Assurance (QA)
1. Each hospital participating in the Project shall:
   a. establish a Joint Quality Assurance Committee (Joint QA Committee) with its collaborating tertiary hospital. The membership of the Joint QA Committee shall, at a minimum, include physicians and nurses from ***both*** the Project hospital and the collaborating tertiary hospital.
   b. convene the Joint QA Committee at least annually to review the care provided to patients under the Project. This review process shall focus on patient outcomes and at a minimum include an assessment of the appropriateness of the selection of each patient entered into the Project; all

[2] The DPH hospital licensure regulations related to cardiac catheterization services include the word "angioplasty". The regulations will be updated to reflect current terminology, i.e., PCI.

complications; any adverse outcomes; number of patients requiring and reason for transfer to a tertiary facility; the technical quality of the catheterization and PPCI procedures performed; and the "door to cath lab time" and "door to treatment time".

c. develop and implement a plan of correction for any problems identified.
d. develop a process for including the findings of the Joint QA Committee's review in the Project hospital's Quality Assurance Program.
e. prepare and maintain a report (Minutes) of each meeting of the Joint QA Committee that must be easily retrievable and available when requested by the Department.

2. All interventional cardiologists shall participate in the Project QA process and attend a minimum of 1 meeting of the Joint QA Committee/year.

VI. Operation of the Project

A. Hospitals shall participate in the Massachusetts PCI peer review and oversight process as outlined by the Department.

B. The Department, with the assistance of the ICSAC/PCI Oversight Subgroup, will review hospital reports of cases that did not meet the clinical inclusion criteria for the project and other issues, as determined by the Department.

VII. General Provisions

A. All hospitals must fully comply with all of the above conditions for continued participation in the Project; failure to do so will result in the withdrawal of approval to perform PPCI.

B. The Invasive Cardiac Services Advisory Committee (ICSAC) will review the reports and data submitted and advise the Department in its ongoing review of current policies and regulations relative to the Project.

REFERENCES:

MA Department of Public Health, Division of Health Care Quality; **Hospital-Based Adult Cardiac Catheterization Services Licensure Regulations** (105 CMR 130.900 through 130.982)

Attachment A

Massachusetts Department of Public Health
Bureau of Health Care Safety and Quality

Project to perform PPCI without onsite open-heart surgery

Guidelines for Development of Collaboration Agreement

Hospitals participating in the Project to provide PPCI services without onsite open-heart surgery must maintain a collaborative association with a tertiary hospital. In this context a tertiary hospital is defined as a hospital which has onsite open-heart surgery.

The purpose of this collaborative association is:

- to provide to the Project hospital's staff with an appropriate environment for the clinical phase of the staff training program.
- to provide ongoing availability of expert consultation to medical and nursing staffs at the Project hospital in the care of patients that have a PPCI procedure performed.

The collaboration agreement at a minimum must:

- be *current* and *specific* to the applicant hospital's participation in the Project and the services/support that the tertiary hospital agrees to provide.
- be developed through the participation of all appropriate disciplines (at a minimum: physicians, nurses and hospital administrators) from ***both*** the Project hospital and the tertiary hospital.
- be signed by the CEO of each hospital and the Director of the Cardiac Catheterization Service or the Director of the Cardiology Services of each hospital.
- include the names of the lead physicians and nurses for the Project at ***each*** facility.
- delineate the joint development of educational program for each group of staff (physicians, nurses and technicians). At a minimum include:
    - names of the staff person/s, at each facility, who is/are responsible for the development, coordination and implementation of the education and training programs.
    - process for the joint development, coordination and implementation of the education and training programs.
    - provisions for Project hospital staff (including all nursing and technical staff) of the cardiac catheterization service to participate in "one to one" observational training at the tertiary hospital.
- include terms specifying that the tertiary facility will provide, through its medical and nursing staffs, 24-hour availability for immediate patient care consultation.
- include provision for the services of appropriate tertiary hospital nursing staff to provide consultation and assistance to the nursing staff at the Project hospital in the development of written nursing care plans and critical pathways.
- include provision for the joint development of competency and performance evaluations of all Project hospital staff and any retraining programs which may be required.
- include provision for ongoing assistance to the Project hospital for staff education.

- delineate the plan for the joint development of a quality assurance review program at the Project hospital which focuses on patient outcomes. At a minimum include the following:
    - job titles of members of the Joint Quality Assurance Committee (Joint QA Committee), which shall include physicians and nurses from each hospital.
    - the frequency of Joint QA Committee meetings. At a minimum the committee shall meet once a year.
    - the process for developing and implementing a plan of correction for any problems identified.
    - the process for including this quality review assessment in the Project hospital's Quality Assurance program.
- include guidelines for the selection of patients to have PPCI performed, with specific reference to the Project requirements.
- include specific provisions for the emergency and routine transfer of patients. At a minimum the following must be delineated:
    - protocol specifying the responsibilities of each hospital's physician and nursing staffs in addressing any emergent situations.
    - the tertiary hospital's agreement to accept, without delay, any patient referred emergently. The tertiary hospital's cardiac surgery staff and facilities shall be immediately available if needed
    - transport will require rapid and efficient transfer, specifically: ambulance transport must be on site or arrive on-site at the non-SOS hospital within 30 minutes of request by catheterization staff due to procedural complication. Every effort must be made to ensure arrival of the patient at the SOS hospital within 60 minutes of decision to transport the patient.
    - the pertinent patient information required, the agreed upon cardiac catheterization image standard, and the method of transmission of this information to the tertiary facility in a timely manner. Information to accompany the patient during transfer should be identified.
    - which facility is responsible for arranging the safe and expeditious physical transfer of the patient and his/her personal belongings.
    - who shall accompany the patient during the transfer.
- include provisions to affirm that both hospitals will provide all patient information required by the Department in a timely manner.

Attachment B

Monthly PPCI volume/outcome report now submitted online via excel spreadsheet

General Instructions

1. Hospitals should complete all 3 tabs in this excel file and send them via e-mail to Gail Palmeri (gail.palmeri@massmail.state.ma.us) on the first of the month. If the first of the month falls on a weekend or holiday, the file should be submitted on the next business day.

2. If you need extra rows for your data, please insert a new row into the spreadsheet.

3. No patient-identifying information should be included in this spreadsheet. Any document with patient-identifying information that has to be sent to the Department must be sent via fax to 617-753-8095. Please address your fax to Gail Palmeri's attention.

4. If you have any questions on how to complete this information, please contact Gail Palmeri at 617-753-8230 or gail.palmeri@massmail.state.ma.us

Hospital Information

1. The hospital information tab contains identifying information about your facility and your staff. Many of these responses may stay the same from month to month. Please be sure to update questions 2 and 3 with the proper date.

PPCI

1. In August 2013, this spreadsheet replaced the paper version of the Monthly PPCI Procedure Volume Report. The questions have recently been revised. This tab should be filled out for each patient who has a PPCI.

2. In addition to completing the patient volume/outcome report, please be sure to answer the 3 additional questions below that ask about total number of primary angioplasties performed in the reporting period, median door-to-balloon (D2B) time and percent of emergency PCI patients with D2B over 90 minutes.

3. Please note that if you are required to submit cardiac catheterization notes, emergency department notes or discharge summaries they must be faxed to Gail Palmeri at 617-753-8095.

Field		Hospital Response	
1.	Hospital Name:		
2.	Period of Report:		
3.	Date of Report:		
4.	Physician Director:		
5.	Nurse Coordinator:		
6.	Data Coordinator:		
7.	Report Completed by:		
8.	Contact Phone Number:		
9.	Contact E-mail Address:		
10.		**Full Name**	**Initials**
	Full Name and Initials of Physicians Providing PCI:		

PPCI Monthly Volume/Outcome Report				
Patient #	Date (MM/DD/YY)	Initials of MD Performing PPCI[3]	Check box if patient was in cardiogenic shock	Patient outcome (Enter codes from below[4])
1				
2				
3				
4				
5				
6				
7				
8				

Total number of primary PCIs performed (during reporting period):	
Median Door to Balloon Time:	
% of total emergency PCIs with D2B over 90 minutes:	

[3] Data entry only –physician's signature is not necessary

[4] Outcome codes, if applicable:

1= Death in the Project hospital during index hospitalization or within 24 hours of discharge;

2=Emergency CABG within 24 hours of PCI procedure*

*****"Emergency" is defined as a sudden and often life-threatening mishap that arises in the course of and ***as a result of*** the performance of a cardiac catheterization and/or PCI procedure. This does not include patients either transferred directly from the cardiac catheterization procedure room or taken within 24 hours to the operating room for surgical correction of emergent/life threatening cardiac disease.